HFA-305
DMB

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
Rockville MD 20857

The Weinberg Group, Inc.
Attention: Nicholas Fleischer, R. Ph., Ph.D.
1220 19th Street, N.W., Suite 300
Washington, D.C. 20036-2400

AUG - 9 2002

Docket No. 99P-5453/CP1

Dear Dr. Fleischer:

This is a correction to the Food and Drug Administration's (FDA) petition response dated June 13, 2000, that granted permission to file an ANDA for Acyclovir Dispersible Tablets, 400 mg and 800 mg. Your petition was originally filed on December 20, 1999.

The Labeling and Nomenclature Committee (Committee) of the Center for Drug Evaluation and Research (Center) has reviewed the term for your proposed dosage form. It was concluded that the terminology "Dispersible Tablets" is not optimal for this dosage form. The Committee determined that the optimal nomenclature for this dosage form would be either "Tablets for Oral Solution", or Tablets for Oral Suspension." The Center concurred with this recommendation. In addition, you have informed the FDA that this product forms a suspension when mixed with an appropriate liquid. Therefore, the FDA is recommending that appropriate term that should be applied to this dosage form is "Tablets for Oral Suspension".

A copy of this letter approving your petition will be placed on public display in the Dockets Management Branch, Room 1061, Mail Stop HFA-305, 5630 Fishers Lane, Rockville, MD 20852.

Sincerely yours,

Gary J. Buehler
Acting Director
Office of Generic Drugs
Center for Drug Evaluation and Research

99P-5453

LET 1